DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 0-793/S-015

Wallace Laboratories
Division of Carter-Wallace, Inc.
Attention: llona J. Scott
Half Acre Road/ P.O. Box 1001
Cranbury, NJ 08512-0181

NOV 4 1998

Dear Ms. Scott:

Please refer to your supplemental new drug application (S-015) dated November 5, 1985, received November 12,1985, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Butisol Sodium (butabarbital Sodium Tablets) 15 mg, 30 mg, 50 mg, and 100 mg.

Supplemental application S-015 provides for the voluntary listing of inactive ingredients in the DESCRIPTION section of labeling. The specific additions are as follows:

> Other ingredients in the Tablets are: calcium stearate, corn starch, dibasic calcium phosphate, FD&C Blue No. 1 (15 mg and 30 mg only), FD&C Blue No. 2 (100 mg only), FD&C Red No. 3 (15 mg and 100 mg only), FD&C Yellow No. 5 (30 mg and 50 mg only - see Precautions), FD&C Yellow No. 6 (100 mg only). Other ingredients in the Elixir are: D&C Green No. 5, edetate disodium, FD&C Yellow No. 5 (See Precautions, flavors (natural,and artificial),propylene glycol, purified water, saccharin sodium, sodium benzoate.

Labeling changes of the kind which you have proposed under S-015 are permitted by section 314.70(c) of the regulations to be made prior to approval of the supplement. It is understood that the changes described in S-034 have been.implemented.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling (copy code IN-01 10-01) submitted on November 4, 1985. Accordingly, the supplemental application is approved, effective as of the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions concerning this NDA, please contact Mr. Merril Mille, R.Ph., Senior Regulatory Management at (301) 594-5528.

Sincerely yours,

11/2/98

Paul Leber, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research